



## Clinical Edit Criteria Proposal

Drug/Drug Class: Xolair® Clinical Edit  
Implementation Date: December 30, 2004  
Prepared for: Missouri Medicaid  
Prepared by: ACS-Heritage Information Systems, Inc.

☒ New Criteria

☐ Revision of Existing Criteria

### Executive Summary

**Purpose:** Ensure appropriate utilization and control of Xolair®(Omalizumab).

**Why was this  
Issue  
Selected:**

This product is indicated in the treatment of moderate to severe asthma in adults and adolescents with perennial allergic asthma not controlled with inhaled steroids. The product shows efficacy in reduction of exacerbations in asthma patients with IgE-mediated diseases. However, with the recommended dosage and administration of 150-375mg SQ every 2-4 weeks, the cost of the drug is a concern.

Program-specific information:	Drug	Package Size	Cost per Vial
	<ul style="list-style-type: none"><li>Xolair® is supplied as a lyophilized sterile powder for injection.</li></ul>	150mg/vial	\$542.00 AWP

**Setting & Population:** Adults and adolescents with perennial allergic asthma

**Type of Criteria:** ☐ Increased risk of ADE  
☒ Appropriate Indications

☐ Non-Preferred Agent  
☐

**Data Sources:** ☐ Only administrative databases

☒ Databases + Prescriber-supplied

## Setting & Population

- Drug class for review: Omalizumab (Xolair®)
- Age range: 12 years of age and older
- Gender: Male and female

## Approval Criteria

- 1) In order to be approved for omalizumab, a patient must meet all three of the below criteria (i.e., asthma diagnosis, prescription drug claim history indicating inadequately controlled asthma, and skin testing).
- 2) Trial and Failure on Inhaled Corticosteroids in the last 45 days.
- 3) In some cases, the call center's clinical consultant may request a consultative specialist (i.e. allergist, immunologist) to provide oversight to therapy.

Approval Diagnoses				
Condition	Submitted ICD-9 Diagnoses	Inferred Drugs	Date Range	Client Approval (Initials)
Asthma	493.0, 493.1, 493.9	N/A	730 days	
Inadequately controlled asthma	N/A	<ul style="list-style-type: none"> <li>Inhaled corticosteroids <b>and</b></li> <li>Short-acting beta<sub>2</sub> agonists (excessive use – defined as minimum of 3 inhalers)</li> </ul>	45 days	
			60 days	
		<ul style="list-style-type: none"> <li>Inhaled corticosteroids <b>and</b></li> <li>Short-term steroid use</li> </ul>	45 days	
		<ul style="list-style-type: none"> <li>Inhaled corticosteroids <b>and</b></li> <li>Emergency room visit</li> </ul>	45 days	

Evaluated Procedures		
CPT Description	CPT Codes	Date Range
Percutaneous skin testing	95024, 95028, 95004	3 months

## Denial Criteria

- Absence of approval criteria
- Age < 12 years



## Appendix

ICD-9 Diagnosis Code Definitions	
Condition	Code
Asthma	493.0, 493.1, 493.9
CPT Procedure Code Definitions	
Procedure	Code
Percutaneous skin testing	95024, 95028, 95004